



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,876	08/03/2006	Dietrich H. W. Gronemeyer	GRONEMEYER ET AL-2PCT	7387
25889	7590	12/14/2009	EXAMINER	
COLLARD & ROE, P.C. 1077 NORTHERN BOULEVARD ROSLYN, NY 11576			MILLER, CHERYL L	
			ART UNIT	PAPER NUMBER
			3738	
			MAIL DATE	DELIVERY MODE
			12/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/581,876	Applicant(s) GRONEMEYER ET AL.	
	Examiner CHERYL MILLER	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 5-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Attachment 1</u> . |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 11, 2009 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 1 and 5-18 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 5-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "framework structure has interruptions in each of the two or multiple layers" in line 8. There is insufficient antecedent basis for this limitation in the claim. The claim previously requires the layers to be of the structural part instead of the framework, as currently written, it is unclear which element comprises the layers. Claims 5-18 depend upon claim 1 and inherit all problems with the claim.

Claim Rejections - 35 USC § 102

Art Unit: 3738

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 5, 7, 8, 12, and 14-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Weber et al. (US 2004/0230290 A1). Weber discloses a medical device comprising a deformable structural part (fig.1, 2) with an expandable framework structure (100), formed by a plurality of metallic struts (46, 48; configuration shown in fig.1, 2, or P0054, P0052) connected with one another, the structural part having two or multiple layers (22, 26, 30), the layers having different electrical or magnetic properties (P0040), the framework structure (100) having interruptions (cut portions, step 38 creates interruptions in two layers, see fig.1, 2) in each of the two layers (22, 30) such that closed current paths are avoided (P0024), the interruptions situated in different positions such that the first layer interruptions do not overlap the second layer interruptions (see fig.2, interruptions on layer 22 are spaced 180 degrees or less away from interruptions on layer 30; P0042). Weber discloses a continuous current path from one end to another (when connector struts 48 are all along one side all the way down the stent, current path extends from one end to another; struts 48 at any arrangement locations a, b, c, or d; P0053). Weber shows two conductive layers (22, 30) separated by an insulative layer (26), the layers positioned coaxially (see fig.1). The stent of figure 2 (or disclosed at P0054) has helical path segments that overlap one another (see attachment 1).

Claims 1, 5-6, and 14-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Alt et al. (US 6,767,360 B1, cited previously). Alt discloses a medical implant (stent 10) having a deformable structural part (10) with an expandable framework structure formed of a plurality of metallic struts (21, 22) connected to one another (see fig.1; col.3, lines 41-53), the structural part (10) composed of multiple layers (15, 51, 50), whereby the layers (15, 50, 51) have different electrical or magnetic properties (each is a different material and thickness, thus inherently different properties). Alt discloses the framework to have interruptions in each of the two layers (interruptions of layer 15 are considered **frame apertures 12**; and interruptions of layer 50 are considered **gaps at 60, 65**), such that closed current paths are avoided in the layers (see fig.3). Alt discloses interruptions in different positions that do not overlap one another (**interruptions 60 and 65 of layer 50 do not overlap interruptions 12 of layer 15**, they are spaced longitudinally from one another-it is noted that interruptions are claimed to be in the framework or structural part, however not required to be in the *struts* of each of the two layers-**if the applicant were to claim the struts to comprise the two layers, and the interruptions in each of the two layers of the struts, this would overcome the Alt rejection**). Alt discloses a continuous current path from one end to another in a helix shape (see fig.3) in layer 50, further that two current path segments that are helices are formed (col.8, lines 45-56). Alt discloses current paths connected at a capacitor (73; fig.4). Alt discloses the frequency to be equal to the frequency of the MR device (col.8, lines 9-12). Alt discloses an insulative intermediate layer (51) between conductive material (15, 50). Alt discloses a method of imaging comprising applying a paramagnetic contrast agent (col.7, lines 25-37) during the imaging process to change

Art Unit: 3738

the properties of the surrounding tissue (which includes the blood, inherently it is matching the susceptibility to the implant, this is the purpose of the paramagnetic contrast agent).

Claims 1 and 5-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Melzer et al. (US 6,280,385 B1, cited in IDS). See figures 3, 4b and respective portions of the specification. Melzer discloses a medical implant (stent 1; fig.1) having a deformable structural part (2) with an expandable framework structure (col.7, lines 22-29) formed of a plurality of metallic struts interconnected (see fig.1, 3, forming diamond mesh-like structure) and wherein the structural part is composed of multiple layers (82, 81, 82; fig.4b), whereby the layers (81, 82, 82) have different electrical or magnetic properties (inherent, as they are disclosed to be different materials). Melzer discloses the framework (2) to have interruptions in each of the two layers **(interruptions in inner layer 82 are considered apertures in stents between diamond struts, seen in fig.3; interruptions in outer layer 82 are considered gaps 91; shown in fig.3, 5; gaps 91 do not overlap stent apertures-space between struts)**, such that current paths that are closed are avoided (path shown by arrows in fig.3 extending from one end of the stent to the other, not closed in the layer), the interruptions (space between struts and 91) situated such that they do not overlap one another. **If the applicant were to claim the *struts* to comprise the two layers, and the interruptions in each of the two layers of the *struts*, this would overcome the Melzer rejection**

Melzer discloses a continuous current path from one end to another in a helix shape (fig.3) of outer layer 82 for example, further that two current path segments (one on each layer 82; col.9 line 65-col.10 line 4) that are helices are formed. Melzer discloses current paths

Art Unit: 3738

connected at a capacitor (3; fig.2a-2g; col.7, lines 50-58). Melzer discloses the frequency to be equal to the frequency of the MR device (col.8, lines 12-16). Melzer discloses an insulative intermediate layer (81; fig.4b) between conductive material (82's).

Claims 1, 5-6, and 14-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Weber et al. (US 2004/0158310 A1, cited previously). Weber discloses a medical implant (stent 320; fig.3a-3c) having a deformable structural part with an expandable framework structure (seen in fig.3a) formed of a plurality of metallic struts interconnected (filaments 322) and wherein the structural part is composed of multiple layers (see fig.3b; each filament has 3 layers and filaments also overlap thus 6 layers in some areas of stent), whereby the layers (334, 330, 334) have different electrical or magnetic properties (inherent, as they are disclosed to be different materials). Weber discloses the framework to have interruptions (breaks in insulation along some filaments; shown in fig.3c) in two of the layers (insulation of overlapping filaments are the interrupted layers), such that current paths that are closed are avoided (path follows one filament from one end of the stent to the other in a helical pattern, see fig.3a; no overlap occurs since at the overlap points, at least one layer is insulation is blocking the current path), the interruptions (gaps of insulation, see in fig.3c for example) situated such that they do not overlap one another (the insulation on two overlapping filaments is not interrupted in the same location, at least one layer of insulation must be present; P0032; thus one filament may have a break in insulation at one intersection while a different filament will have a break in insulation at a different intersection). **If applicant were to distinguish in the claims such that the interruptions are in conductive layers (verses the insulative layers of Weber), this would**

Art Unit: 3738

seemingly overcome the Weber rejection). Weber discloses a continuous current path from one end to another in a helix shape (fig.3a), further that two current path segments (one on each filament) that are helices are formed. Weber discloses current paths to be in opposite helical directions (P0028; P0039).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alt et al. (US 6,767,360 B1, cited previously) in view of Unger (US 6,884,407 B1, cited previously). Alt discloses a method of MR imaging a medical implant comprising applying a paramagnetic contrast agent near the medical implant in order to regulate the susceptibility of the tissues surrounding the medical implant (col.7, lines 25-37), however is silent to mention any particular contrast agents. Unger teaches in the same field as MR imaging, the use of ferrites as known contrast agents in the field of imaging (evidence of a known particular example) for providing a sufficient image of tissue (metal oxides, iron oxides, col.3, lines 35-59). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Unger's evidence of known specific contrast agents (ferrites) for MR imaging, with the MR imaging process of Alt in order to provide an image that distinguishes the tissue.

Conclusion

Art Unit: 3738

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERYL MILLER whose telephone number is (571)272-4755.

The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/
Examiner, Art Unit 3738

/DAVID ISABELLA/
Acting SPE of Art Unit 3738